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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,692	07/28/2003	Brent L. Atkinson	CRM-P15F/P	5172

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EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
09/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/628,692	ATKINSON ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response filed on June 15, 2007 have been received and entered into the case. Claims 15 – 18 are canceled; claims 1 – 14 and 19 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 112

Rejections under 35 U.S.C. 112, second paragraph, are withdrawn due to amendment.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1, 3 – 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gertzman.

Applicant claims a bone repair material comprising a porous, resorbable particulate derived from anorganic or natural bone mineral, or synthetic hydroxyapatite in an amount of at least 50%; and a resorbable carrier gel forming a putty like formulation; wherein the gel has a molecular weight and concentration to facilitate bone repair and minimalize migration and expansion of the material. The particulate is hydroxyapatite with a particle size of 300 – 1000. The gel comprises a polysaccharide; hyaluronic acid, derivatives thereof, hydroxypropyl cellulose, or mixtures thereof; the gel is hyaluronic acid with a molecular weight of 0.7 – 2 x10^6 daltons and a concentration of 45 – 64 mg/cc in the putty. Applicant claims a bone repair material for dental bone repair comprising 30 – 75% of a porous, resorbable, hydroxyapatite or anorganic done derived particulate; and 25 – 70% of a hyaluronic acid gel; wherein the material is a moldable putty and the amount of particulate is dependent on its density

Gertzman teaches a putty for repairing bone (abstract) comprising bone powder with a particle size of about 100 – 850 um and high molecular weight gel (abstract). The bone particles are 100 – 450 um (col.4 line 63-65) and are combined with hyaluronate (hyaluronic acid) with molecular weights of 7x10^5 – 3x10^6 daltons (col.5 line 1-10). Other compositions may include hyaluronic acid and up to 75% bone particles with 250 – 850 um diameters (col.5 line

57-61). Additional substances can be added to the bone putty such as collagen, hydroxyapatite, or peptide (col.5-6).

Gertzman does not teach the composition comprising the claimed concentrations or percents of components. However, Gertzman teaches the carrier gel has a molecular weight high enough to provide a malleable (moldable) putty and be present in low amounts (col.4 line 8-23). Gertzman additionally provides examples with varying amounts of particles and carrier gel, dependent on particle size and molecular weights (see examples), to ensure a putty formulation. Thus, as evidenced by Gertzman the amounts and concentrations of the components are result effect variables. Therefore, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to optimize the amounts of ingredients in the composition of Gertzman as a matter of routine practice. Moreover, in following the teachings of Gertzman, one of ordinary skill in the art would have been motivated by Gertzman to optimize the amounts of gel and particulates with a reasonable expectation for successfully obtaining an effective putty like material for repairing bone.

4. Claims 1 – 14 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gertzman in view of Tofe (US 2003/0143283 A1).

Applicant claims a bone repair material comprising a porous, resorbable particulate derived from anorganic or natural bone mineral, or synthetic hydroxyapatite; and a resorbable carrier gel forming a putty like formulation; wherein the gel has a molecular weight and concentration sufficient to facilitate bone repair and minimalize migration and expansion of the material. The particulate is bovine derived and has a particle size of 250 – 1000 um; the

particulate is porous hydroxyapatite derived from lime containing algae, with a particle size of 300 – 1000 um. The gel comprises a polysaccharide; comprises hyaluronic acid, derivatives thereof, hydroxypropyl cellulose, or mixtures thereof; is hyaluronic acid with a molecular weight of 0.7 – 2 x10^6 daltons and a concentration of 45 – 64 mg/cc in the putty. The bone repair material further comprises a synthetic type I collagen with a particular polypeptide sequence. The particulate has a density of 1.1 – 1.3 g/cc and the putty comprises 50 – 60 % particulate and 40 – 50 % hyaluronic acid gel; the material comprises about 55% particulate and about 45% hyaluronic acid gel; the particulate has density of 0.45 – 0.65 g/cc and the putty comprises 35 – 40% particulate and 60 – 65% hyaluronic acid gel. The carrier gel is hydroxypropyl cellulose or methylcellulose. The material further comprises a P15 polypeptide collagen with a particular sequence bound to porous hydroxyapatite derived from lime containing algae, with a diameter of about 300 – 1000 um, suspended in hydroxylpropyl cellulose or hyaluronic acid gel; the PEPGEN P15 is present in an amount of at least 800 mg/cc. Applicant additionally claims a bone repair material for dental bone repair comprising 30 – 75% of a porous, resorbable, hydroxyapatite or anorganic done derived particulate; and 25 – 70% of a hyaluronic acid gel; wherein the material is a moldable putty and the amount of particulate is dependent on its density. The material further comprises a P15 polypeptide with a particular sequence that is bound to xenogeneic bone particulate with about 200 – 500 mm diameter, suspended in the carrier gel.

Gertzman teaches a putty for repairing bone (abstract) comprising bone powder with a particle size of about 100 – 850 um and high molecular weight gel (abstract). The bone particles are 100 – 450 um (col.4 line 63-65) and are combined with hyaluronate (hyaluronic acid) with

molecular weights of 7x10^5 – 3x10^6 daltons (col.5 line 1-10). Other compositions may include hyaluronic acid and up to 75% bone particles with 250 – 850 um diameters (col.5 line 57-61). Additional substances can be added to the bone putty such as collagen, hydroxyapatite, or peptide (col.5-6).

Although the reference does not teach the hydroxyapatite is derived from lime containing algae, this limitation is considered to be a product by process type limitations. Thus, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

Gertzman does not teach the putty composition wherein the particulate is bovine or wherein the collagens and peptides have the claimed collagen sequences. However, at the time of the claimed invention, the instant materials were well known and used in the art for bone repair putty composition. In support, Tofe teaches a composite for repairing bone, comprising hyaluronate (hyaluronic acid) and bovine bone particulate or hydroxyapatite (abstract) and peptides such as those claimed (0014). Thus, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use the claimed particulates and collagens in the putty of Gertzman since they were well known and used for their claimed purpose, as evidenced by Tofe.

Gertzman does not teach the composition comprising the claimed concentrations or percents of components. However, Gertzman teaches the carrier gel has a molecular weight high enough to provide a malleable (moldable) putty and be present in low amounts (col.4 line 8-23). Gertzman additionally provides examples with varying amounts of particles and carrier gel, dependent on particle size and molecular weights (see examples), to ensure a putty formulation. Thus, as evidenced by Gertzman the amounts and concentrations of the components are result effect variables. Therefore, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to optimize the amounts of ingredients in the composition of Gertzman as a matter of routine practice. Moreover, in following the teachings of Gertzman, one of ordinary skill in the art would have been motivated by Gertzman to optimize the amounts of gel and particulates with a reasonable expectation for successfully obtaining an effective putty like material for repairing bone.

Response to Arguments

Applicant argues that the references do not teach the claimed amounts of bone particulates; that the compositions of the prior art become less malleable with increased particulate amounts.

However, these arguments fail to persuade because Gertzman teaches bone particles up to 75% and that the carrier is adjusted relative to the amount of bone particles. Furthermore, the reference suggests that the amounts are adjusted to ensure a putty is obtained, suggesting to one of ordinary skill in the art to optimize the amounts and types of carriers as well as particulate,

with a reasonable expectation for successfully obtaining an effective bone repair, putty composition.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 -3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth A. Davis/
Primary Examiner
Art Unit 1651

August 31, 2007